



## Apogee Therapeutics Provides Pipeline Progress and Reports Second Quarter 2024 Financial Results

August 12, 2024

*Continued advancement of pipeline and execution towards expected milestones, including APG777 16-week proof-of-concept data from the Phase 2 Part A trial in 2H 2025, APG808 interim Phase 1 data in 4Q 2024, and APG990 Phase 1 trial initiation in healthy volunteers accelerated to 3Q 2024*

*APG333, a novel subcutaneous half-life extended anti-TSLP antibody, added to portfolio to provide for potential best-in-class combination efficacy across multiple respiratory indications, expected to enter the clinic in 2025*

*Apogee plans combination studies of 777 + 990 (IL-13 and OX40L) and 777 + 333 (IL-13 and TSLP), with the potential for greater efficacy across I&I diseases, starting with the first clinical trial of the APG777 and APG990 combination in 2025*

*\$790 million cash, cash equivalents and marketable securities with runway into 2028*

SAN FRANCISCO and WALTHAM, Mass., Aug. 12, 2024 (GLOBE NEWSWIRE) -- Apogee Therapeutics, Inc. (Nasdaq: APGE), a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other I&I indications, today reported pipeline highlights and second quarter financial results.

"The first half of this year has been marked with significant pipeline progress and a focus on further defining our strategy that will enable us to deliver on our goal of reshaping the standard of care for patients in I&I by developing treatments with potential best-in-class monotherapy and combination efficacy and improved dosing schedules," said Michael Henderson, M.D., Chief Executive Officer of Apogee. "A key component of that strategy is combining several of our pipeline programs, including APG333, which is our newly added compound targeting TSLP. TSLP is a validated target with one compound approved for asthma without a biomarker requirement, and which has recent clinical data demonstrating potential for treatment of a broader respiratory disease population, including COPD. We have strategically built a unique portfolio of IL-13, IL-4R $\alpha$ , OX40L and TSLP inhibitors that enable multiple combinations in dermatology and respiratory diseases with the potential for deeper and broader responses. With our continued execution of the pipeline, our expected milestones are on track and we have a strong cash position taking us into 2028. We look forward to discussing our programs and additional plans for combination approaches in further detail at our R&D Day in December this year."

### *Pipeline and Corporate Highlights and Upcoming Milestones*

- o **First patient dosed in APG777 Phase 2 trial and on track for Part A data in 2H 2025:** APG777 is a novel, subcutaneous (SQ) extended half-life monoclonal antibody (mAb) targeting IL-13 – a critical cytokine in inflammation and a primary driver of AD.
  - o In May, the company commenced dosing in the Phase 2 clinical trial of APG777 in patients with moderate-to-severe AD; 16-week proof-of-concept induction data from Part A of the trial are expected in the second half of 2025.
  - o The trial is designed to combine the typical Phase 2a and 2b portions of a clinical trial into a single protocol. The primary endpoint of each part of the study is mean percentage change in EASI score from baseline to Week 16.
  - o The Phase 2 APG777 trial in asthma is expected to include APG777 as a monotherapy and APG777 in combination with APG333, combining IL-13 and TSLP inhibition, pending Phase 1 clinical trial data from APG333.
- o **Phase 1 APG990 HV clinical trial set to start ahead of schedule in 3Q 2024:** APG990 is a novel, SQ half-life extended mAb targeting OX40L, initially being developed for AD. OX40L is located further upstream in the inflammatory pathway than IL-13 or IL-4R $\alpha$  and targeting it could have broader impact on the inflammatory cascade by inhibiting Type 1, Type 2 and Type 3 pathways. With current approved biologics only targeting two mechanisms of action (IL-13 and IL4R $\alpha$ ) in AD, OX40L could represent another therapeutic option for patients, especially the portion of patients who do not benefit from currently available treatments. In addition, based on our preclinical studies, we believe APG990 can be dosed every three to six months in maintenance, which, if our clinical trials are successful, would represent a significant improvement compared to first generation OX40L antibodies that are expected to be dosed every four to twelve weeks.
  - o The company has received regulatory clearance in Australia and plans to initiate a Phase 1 APG990 clinical trial in HVs in the third quarter of 2024 with interim data expected in 2025.
- o **Phase 1 APG808 trial on track for 4Q 2024 interim data readout:** APG808 is a SQ extended half-life mAb targeting IL-4R $\alpha$ , a target with clinical validation across eight Type 2 allergic diseases. APG808 has similar binding affinity for IL-4R $\alpha$  as a first generation mAb, DUPIXENT, and has demonstrated similar inhibition to DUPIXENT across three in vitro assays that measure downstream functional inhibition of the IL-13/IL-4 pathway (pSTAT6 induction, inhibition of TF-1 proliferation, and inhibition of TARC secretion).
  - o The company expects to share interim data from the Phase 1 HV clinical trial in the fourth quarter of 2024.

- Pending results of the Phase 1 HV clinical trial, Apogee plans to initiate a Phase 1b clinical trial in asthma with data expected in the first half of 2025.
- **APG333, a novel SQ half-life extended anti-TSLP antibody, added to portfolio earlier in the year, with supporting third-party evidence of broad potential of target inhibition in asthma and COPD:** APG333 is a fully-human mAb targeting thymic stromal lymphopoietin (TSLP). TSLP is an epithelial cell-derived cytokine that has emerged as an attractive validated target for the treatment of I&I indications, with the potential to be used in combination with other mAbs for potentially greater efficacy in broader populations. TSLP plays important roles in Type 2 and Type 3 inflammation, particularly in both eosinophilic and non-eosinophilic inflammation. TSLP inhibition has been clinically validated, with one approved product on the market for the treatment of severe asthma without biomarker or phenotype restrictions. Based on its mechanism, TSLP inhibition could offer treatment to the approximately 40% of severe asthma patients with low Type 2 inflammation.
  - The company plans to nominate a development candidate by the end of 2024 and initiate a Phase 1 APG333 clinical trial in healthy volunteers (HV) in 2025.
  - Pending Phase 1 data, the company has the opportunity to combine APG333 with APG777, combining IL-13 and TSLP inhibition, to drive potential best-in-class efficacy in respiratory indications.
- **Potential to expand patient reach with best-in-class efficacy and dosing with planned APG777 and APG990 combination approach, combining IL-13 and OX40L inhibition:** Apogee plans to develop APG777 and APG990 together as a potential first-in-class coformulation combining deep and sustained inhibition of Type 2 inflammation via APG777's inhibition of IL-13 with broader inhibition of Type 1-3 inflammation through APG990's inhibition of OX40L. These combined mechanisms offer the potential for improved clinical responses over monotherapy across a variety of I&I diseases while our approach of coformulating two extended half-life mAbs holds the potential for best-in-class dosing.
  - The company plans to initiate the first clinical trial of the APG777 and APG990 combination in 2025.
- **Expanded board of directors:** In May, drug development expert Lisa Bollinger, M.D., joined Apogee's board of directors. Dr. Bollinger has over 30 years of experience in drug development, with deep regulatory experience gained within both the U.S. FDA and multinational biotechnology and pharmaceutical companies, and most recently served as Vice President, Regulatory Affairs, Global Regulatory Affairs and Clinical Safety at Merck, where she led the general medicine therapeutic area in regulatory affairs.
- **Apogee Therapeutics 2024 Virtual R&D Day to be held in December:** The company plans to highlight progress across its pipeline and showcase its path to reshaping the standard of care in I&I by bringing forward monotherapy and combination treatments that offer the potential for best-in-class efficacy and improved dosing.

#### *Second Quarter Financial Results*

- **Cash Position:** As of June 30, 2024, Apogee had cash, cash equivalents and marketable securities of \$789.6 million. Apogee expects that its existing cash will enable it to fund its current operating expenses into the first quarter of 2028.
- **Research & Development (R&D) Expenses:** R&D expenses for the second quarter of 2024 were \$33.2 million, compared to \$13.9 million for the second quarter of 2023. R&D expenses increased primarily due to further development of the company's APG777, APG808 and APG990 and APG333 programs and advancement of its pipeline into clinical trials, preclinical testing of potential combinations, as well as increases in personnel costs, including equity-based compensation expense, associated with the growth of its R&D team.
- **General and Administrative (G&A) Expenses:** G&A expenses for the second quarter of 2024 were \$10.9 million, compared to \$4.9 million for the second quarter of 2023. G&A expenses increased primarily due to increases in personnel costs, including equity-based compensation, associated with the growth of the company's G&A team, as well as increased costs related to being a public company, including for legal, IT and professional services, and to support the growth of the business.
- **Net Loss:** Net loss for the second quarter of 2024 was \$33.8 million, compared to the net loss for the second quarter of 2023 which was \$18.9 million. Net loss increased primarily as a result of higher R&D and G&A expenses as described above, partially offset by higher interest income.

#### **About Apogee**

Apogee Therapeutics is a clinical-stage biotechnology company advancing novel biologics with potential for differentiated efficacy and dosing in the largest inflammatory and immunology (I&I) markets, including for the treatment of atopic dermatitis (AD), asthma, chronic obstructive pulmonary disease (COPD) and other I&I indications. Apogee's antibody programs are designed to overcome limitations of existing therapies by targeting well-established mechanisms of action and incorporating advanced antibody engineering to optimize half-life and other properties. APG777, the company's most advanced program, is being initially developed for the treatment of AD, which is the largest and one of the least penetrated I&I markets. With four validated targets in its portfolio, Apogee is seeking to achieve best in class efficacy and dosing through monotherapies and combinations of its novel antibodies. Based on a broad pipeline and depth of expertise, the company believes it can deliver value and meaningful benefit to patients underserved by today's standard of care. For more information, please visit [www.apogeetherapeutics.com](http://www.apogeetherapeutics.com).

## Forward Looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the federal securities laws, including, but not limited to, statements regarding: Apogee’s plans for its current and future product candidates and programs, its plans for current and future clinical trials, including a Phase 2 trial for APG777 in asthma, a Phase 1b trial of APG808 in asthma, a Phase 1 trial for APG990, and a Phase 1 trial for APG333; Apogee’s plans for clinical trial design; the anticipated timing of the initiation of and results from Apogee’s clinical trials, including data from Apogee’s Phase 2 trial of APG777 and Apogee’s Phase 1 trial of APG808; the potential clinical benefit and half-life of APG777, APG808, APG990, APG333 and any other potential programs, including combination therapies; Apogee’s expected timing for future pipeline updates; and expectations regarding the time period over which Apogee’s capital resources will be sufficient to fund Apogee’s anticipated operations. Words such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “estimate,” “predict,” “potential,” “develop,” “plan” or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While Apogee believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in Apogee’s filings with the U.S. Securities and Exchange Commission (the SEC)), many of which are beyond the company’s control and subject to change. Actual results could be materially different. Risks and uncertainties include: global macroeconomic conditions and related volatility, expectations regarding the initiation, progress, and expected results of Apogee’s preclinical studies, clinical trials and research and development programs; expectations regarding the timing, completion and outcome of Apogee’s clinical trials; the unpredictable relationship between preclinical study results and clinical study results; the timing or likelihood of regulatory filings and approvals; liquidity and capital resources; and other risks and uncertainties identified in Apogee’s Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 5, 2024, Quarterly Report on 10-Q for the quarterly period ended March 31, 2024, filed with the SEC on May 13, 2024, and subsequent disclosure documents we may file with the SEC. Apogee claims the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. Apogee expressly disclaims any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

## APOGEE THERAPEUTICS, INC. CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(In thousands, except unit/share data)

	<u>JUNE 30, 2024</u>	<u>DECEMBER 31, 2023</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 307,299	\$ 118,316
Marketable securities	368,929	277,143
Prepaid expenses and other current assets	5,625	2,950
Total current assets	681,853	398,409
Long-term marketable securities	113,395	—
Property and equipment, net	714	377
Right-of-use asset, net	4,227	2,217
Other non-current assets	468	401
Total assets	\$ 800,657	\$ 401,404
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,527	\$ 2,143
Lease liability	1,682	1,101
Accrued expenses	17,408	17,314
Total current liabilities	24,617	20,558
Long-term liabilities:		
Lease liability, net of current	2,401	933
Total liabilities	27,018	21,491
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Common Stock; \$0.00001 par value, 400,000,000 authorized, 58,481,214 issued and 56,676,465 outstanding as of June 30, 2024; 400,000,000 authorized, 50,655,671 issued and 48,338,769 outstanding as of		—

December 31, 2023		
Additional paid-in capital	963,607	503,354
Accumulated other comprehensive (loss) income	(289)	329
Accumulated deficit	(189,680)	(123,770)
Total stockholders' equity	<u>773,639</u>	<u>379,913</u>
Total liabilities and stockholders' equity	<u>\$ 800,657</u>	<u>\$ 401,404</u>

**APOGEE THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS**  
**(UNAUDITED)**

	THREE MONTHS ENDED JUNE 30,		SIX MONTHS ENDED JUNE 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 33,206	\$ 13,946	\$ 61,922	\$ 22,401
General and administrative	10,916	4,939	20,381	9,142
Total operating expenses	<u>44,122</u>	<u>18,885</u>	<u>82,303</u>	<u>31,543</u>
Loss from operations	(44,122)	(18,885)	(82,303)	(31,543)
Other income, net:				
Interest income, net	10,306	—	16,393	133
Total other income, net	<u>10,306</u>	<u>—</u>	<u>16,393</u>	<u>133</u>
Net loss	<u>\$ (33,816)</u>	<u>\$ (18,885)</u>	<u>\$ (65,910)</u>	<u>\$ (31,410)</u>

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